RECORD OF ORAL HEARING

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte JACK L. ARBISER

Appeal 2007-0091
Application 09/765,491
Technology Center 1600

Oral Hearing Held: February 6, 2007

Before TONI R. SCHEINER, ERIC GRIMES, and NANCY LINCK,
Administrative Patent Judges

ON BEHALF OF THE APPELLANT:

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The above-entitled matter came on for hearing on Tuesday, February 6, 2007, commencing at 9:20 a.m., at The U.S. Patent and Trademark Office, 600 Dulany Street, Alexandria, Virginia, before Christine L. Loeser, Notary Public.

THE CLERK: Calendar number 5, appeal number 2007-0091, Ms. Monheit.

MS. SCHEINER: Good morning.

MS. MONHEIT: Good morning. I'm just going to get three volumes out.

MS. SCHEINER: Take all the time you need. I just want you to know we have something new this morning. This is something that we'll have from now on.

MS. MONHEIT: The court reporter? My name, Rivka Monheit, and I'm here for the appeal under number 09-765491. The applicant is Jack Arbiser. We have seven issues that are on appeal. We got rid of one so I guess we can kind of start running through a few of them.

We have really, for all those issues, really only a few claims that are pending, but there are really three groups of claims. You will see that there are three independent claims, all dealing with methods of treatment, generally dealing with the symptoms associated with angiogenesis and inhibiting angiogenesis.

I'd like to just start with the section 112 rejection, which is whether claims 4 through 6 and 17 are indefinite. They use the term "effective amount," which is a standard term that we use in method-of-

treatment claims and lots of claims that have been issued with the term effective amount.

As we discussed with the examiner in the appeal brief and in the reply brief, we specifically disclose the disorders that are being treated. We specifically disclose in the claims the agents that are being used and one of ordinary skill in the art would know how to determine an effective amount.

Even in the specification, we give examples of how to do that. I believe at page 14, we talk about typical assays that are used in vitro and in vivo, and specifically -- this would be at line 28 through 30 -- we say the angiogenesis inhibiting formulation as administered is required to alleviate systems disorders.

The assays can be performed to determine effective amount of the agent either in vitro or in vivo and then we discuss representative assays and mention that many others are known in the art. However, we give certain examples in the examples.

Therefore, we believe that one of ordinary skill in the art would know what we meant by using this term and would understand the scope of the claim and how to practice it.

With respect to -- moving on to the prior art rejections, with respect to claim 17, this claim has been rejected for lack of novelty over one reference, the 368 patent to Wirostko.

It's a very short patent and it really is dealing with age-related macular degeneration. They discuss how -- they had noticed when -- I believe when tetracyclines were being administered systemically for

treatments of other disorders, they actually noticed that people could see better and so they thought that was an unexpected result and therefore filed the patent.

There is the use of a term in this application when they are talking about these other disorders that are being treated. They say that -- the people who in column 3, at the beginning of column 3, they say that the people who are being treated had a variety of varied medical history and mentioned a bunch of different problems that they had.

They had chronic rheumatoid arthritis, acne rosacea, chronic dermatitis without keratitis, and they were treated with tetracycline or minocycline. It is actually not exactly clear what each person had or when they had it or anything. That is really not their focus. Their focus is on age-related macular degeneration and the improvement of peoples' vision.

JUDGE GRIMES: I think what the examiner was pointing to was in column 2 where they are talking about a prior art study.

MS. MONHEIT: It's the same study.

JUDGE GRIMES: Okay. Cites it's being used as therapy for acne rosacea.

MS. MONHEIT: Right. This is same study that they are they are talking about in both sections. At the bottom of column 3, they are saying also to the brown study, at least the way I read it, is they are talking about same study.

We cited back to the examiner and provided evidence that this term acne rosacea is actually many times misused and may have been misused in this context as well.

It is really just not clear that what they are doing but what does appear to be clear from the treatment is that it looks like they were administering an effective amount for inhibiting the bacteria growth which would normally be associated with acne and not be associated with rosacea.

There are some references we printed out from the rosacea.org website that go into discussion about how people have problems even determining when someone has rosacea and what are the various characteristics and phases.

But there is a quote in there where they clearly state that is a -- people have often times misused this term for adult acne and called it rosacea when, in fact, these are really unrelated disorders.

JUDGE GRIMES: Could you point us to the page and line number for that?

MS. MONHEIT: I'm sorry?

JUDGE GRIMES: The page and line number of that quote?

MS. MONHEIT: I'll see if I can find it. It's in this printout.

JUDGE GRIMES: I did read that and I didn't see the word acne in it.

MS. MONHEIT: Okay. It's -- well, I have it as a separate printout. It's page 1 of 1 in rosacea.org printout. There were two printouts that should have been submitted.

It says, Question, is there a difference between rosacea and adult acne? Answer, although rosacea sometimes has been referred to as adult acne, it is a distinctly different disease than acne. The bumps and pimples of adult acne resemble the papules and pistules of sub-type 2

rosacea but there are a number of important differences between the two disorders.

Unlike rosacea, which typically appears in the central face area, acne often appears on a lateral as well as the central face, especially in older teens. Also unlike acne, rosacea does not include the comedones, commonly known as blackheads. In further contrast to acne, rosacea is usually associated with flushing and other signs and symptoms are frequently present.

That's what we are referring to.

JUDGE GRIMES: Right. Which says that acne is different from rosacea.

MS. MONHEIT: Right. And if you look at --

JUDGE GRIMES: What about the examiner's reference? He's cited a patent that refers to rosacea, originally termed acne rosacea, which seems to suggest that acne rosacea --

MS. MONHEIT: I believe it's more of a misnomer where people are misusing a term, and especially with respect to this particular reference where they use the phrase acne rosacea that, in fact, all they are talking about is acne and there's no disclosure of a treatment of rosacea per se.

JUDGE GRIMES: It's the patent that refers to acne rosacea. What we have is the citation -- the title of the citation that is diagnosis as the treatment of ocular rosacea and ocular rosacea was one of the four types of rosacea that was referred to in that rosacea.org.

MS. MONHEIT: That's true.

JUDGE GRIMES: So based on the title of the reference, it certainly sounds like they are talking about rosacea, not acne.

MS. MONHEIT: I don't know because the reference wasn't brought -- wasn't made of record in this proceeding.

The only thing I can imagine is that -- I really just couldn't postulate about what they may or may not be talking about, but within this patent it appears that the disease and disorder and the amount of tetracycline that's being administered is being administered more for inhibiting bacteria.

And that we didn't see any discussion or disclosure about treatment of rosacea per se in this reference.

Now, to move on to the obviousness type rejections, which are separate from the claim 17 rejection. There are really two groupings of the claims. Claims 4 through 6 and claims 10 through 12 and 18 and 19, so I will deal with them separately and really different references are cited against these different sets of claims.

The main reference that is cited against us with respect to the claims 4 through 6 grouping is the Deutch reference, and we seem to be having this issue about terminology. Definition seems to be reoccurring throughout this appeal.

Deutch has a -- is really focusing on a specific type of drug. They are looking at thrombospondin, peptide fragments and synthetic analogs of thrombospondin. In discussing how thrombospondin can be used, they talk about a whole laundry list of the different things -- how wonderful thrombospondin is.

It can be used for everything, increase this, decrease that and the examiner really focuses on the definition of the angiogenesis activity that is used in this particular reference.

In Deutch it says angiogenesis activity -- this is at column 3, lines 21, 23 -- has the ability to inhibit or enhance the formation of blood vessels.

We were quite surprised by this definition because -- and as you'll see in the other references, I think almost every other reference that is cited as prior art during this proceeding and even all the references or many of -- the references that I looked at in preparation for this, when they talk about angiogenesis, most other references really talk about blood vessel formation.

And in response to the examiner's rejection, we submitted a review article that really focuses on what's similar and what's different between angiogenesis and lymphangiogenesis, and this is the article by Jussila and Alitalo.

And this article really makes it clear that they are not one and the same. There is a lot that's similar. They have a lot of similar growth factors but there are also distinctions that are different and the purposes are different.

I thought it was interesting that this article makes note that really no one was looking into lymphangiogenesis until just, like, a decade ago. On page 678, they say that they really -- people only started to study the mechanisms behind lymphangiogenesis in 1995.

Well, if you look at when the Deutch reference was filed, it was filed in 1990. This was before any of this amazing discussion that is going on in the Jussila article really existed.

People say -- again, we may have the situation where Deutch is speaking broadly. Yes, there are commonalities but didn't really understand that these are distinctive mechanisms and distinctive characteristics.

Therefore, when the examiner is mixing this reference with other references to say angiogenesis and lymphangiogenesis are one and the same, it's really an improper combination.

JUDGE LINCK: Counsel, is it your position it wouldn't be obvious to one skilled in the art to use a drug that is effective for angiogenesis to treat lymphangiogenesis? And even though they have common characteristics --

MS. MONHEIT: Right. I understand they have common characteristics. It's my position that the references that are being cited against us -- and we can walk through them -- they are really talking about specific angiogenesis inhibitors. There's no discussion about treatment of these skin disorders or diseases.

While there is discussion that they anti-angiogenic agents and they have that activity, these are method-of-treatment claims and therefore, there's no hint or suggestion that we would be using it to treat lymphangiogenesis or any of the other number of skin disorders that are discussed.

JUDGE LINCK: I don't think you answered my question.

MS. MONHEIT: I'm sorry.

JUDGE LINCK: Is it your position that it would not be obvious to one skilled in the art to use an anti-angiogenesis drug to treat lymphangiogenesis?

MS. MONHEIT: I mean, I guess the answer would be maybe one would try and see what happens because, as we'll go through in just a little bit more, angiogenesis has so many factors that are involved and so many different mechanisms and pathways that are involved.

And as we see in a number of the references, there are a lot of conflicting opinions about how what is being inhibited, what is being targeted with one drug in one case and what is being targeted in another case. I don't think it would be clear that, oh, of course, it's going to -- if it worked in this case, it would work for a lymphangiogenesis. So I guess the answer would be no.

JUDGE LINCK: Is there any evidence that drugs that are effective in treating angiogenesis are not effective in treating lymphangiogenesis?

MS. MONHEIT: I'm not aware of that. I'm sorry.

So the examiner was relying on Deutch for this particular phrasing and then combining it with other references such as Brem and Andrulis and Teicher. These references all talk about various angiogenesis inhibitors and specific ones. With respect to Brem, it's focusing on the use of tetracycline or minocycline.

Brem specifically teaches that it's looking for a simple organic -- a molecule can be created by simple organic synthesis. This is at column

2, lines 42 through 44. So it's really not looking at these long peptides or proteins. They want something very simple.

The thrombospondin that is disclosed in Deutch is a protein and there's really no disclosure in either of these references that you would take Brem's small minocycline or tetracycline and substitute it for the thrombospondin in Deutch.

Neither of -- and also with respect to Brem, there's no discussion of the specific skin disorders that are listed in the claim. It's really just talking about topically, locally or systemically, using these tetracyclines or minocyclines as angiogenesis inhibitors.

With respect to Andrulis, also Andrulis is focusing just on the use of thalidomide. It mentions that thalidomide, it uses it in treating inflammatory dermatosis.

And it talks about how this thing they disclose using a therapeutically-effective amount for treating the underlying inflammation for these diseases and disorders. Again, none of the disorders they talk about are the ones that are listed in the claim.

JUDGE GRIMES: What about in column 7, lines 3 to 4, molluscum contagiosum. Is that the same as molluscum contagious in line 4?

MS. MONHEIT: I'm sorry? Column 7.

JUDGE GRIMES: Column 7, lines 3 to 4, it has molluscum contagiosum.

MS. MONHEIT: Okay.

JUDGE GRIMES: In your claim 4, lines 3 to 4, it has molluscum contagious. Are those the same or is there a difference?

MS. MONHEIT: That should be the same. I believe that's the same. With respect to Andrulis, however, it's talking about the -- using an effective amount to treat the inflammation. I don't believe that it's discussing using an effective amount for inhibiting angiogenesis per se. As discussed in -- I'm not sure which reference.

I think it's the lymphangiogenesis versus angiogenesis review, I think there's a discussion about how many times angiogenesis has a lot of inflammation associated with it, but these are not -- they are not one and the same, and that you can treat the inflammation and you can treat the angiogenesis.

And sometimes you'll treat both of them, but there is not necessarily the same amount so you use it to treat one versus the other.

With respect to Teicher, this one was interesting because they are really talking about administering -- they have got these tumors that they want to enhance the ability of chemotherapeutic agents to really attack these tumors.

And they notice that because of the hypoxia that occurs in the tumors, the chemotherapeutic agents just aren't effective, so they are adding hemoglobin and then optionally adding a chemotherapeutic agent, preferably adding them together and then they also disclose that they could add an anti-angiogenic agent such at the TNP 470 or minocycline.

Again, here they are focusing on how to increase tumor oxygenation and then treat it with a chemotherapeutic.

So they do mention that TNP 470 is an anti-angiogenic agent which we disclose in our application, but there's no discussion or suggestion about treating the specific skin disorders that are listed in claim 4 in the Teicher reference nor there is no discussion or suggestion to substitute these agents with the ones that are disclosed by Deutch.

Again, Deutch was really looking at how this particular thrombospondin and different fragments and all the wonderful things that it can do. It has this huge laundry list of the different ways that it can be used.

So the examiner is really picking from one reference and choosing from another reference and just putting them together, and this is, in some ways, the hindsight analysis that has been -- that we've been told not to engage in, that the Federal Circuit has said over and over that you have to have these specific teachings and suggestions to combine these references.

And you have to look at the reference as whole and what the whole reference is teaching and not just choose one sentence here and choose another sentence here and say, Aha, they have got your claim.

JUDGE GRIMES: I have a more general question. The review article that you submitted is talking about lymphangiogenesis as the normal process of creating new lymph ducts, whatever it is.

MS. MONHEIT: Yes.

JUDGE GRIMES: How is lymph angiogenesis a skin disorder like you have recited in your claim? I'm just wondering why you would want to inhibit lymphangiogenesis as a therapeutic measure. I know of angiogenesis in tumors, but where's the connection of lymphangiogenesis with a with a skin disorder?

MS. MONHEIT: I don't know. I mean, if you have a broad definition of skin disorder, I definitely can think of examples.

JUDGE GRIMES: It's listed in your specification, Representative skin disorders include. I'm curious about what kind of thing.

MS. MONHEIT: I can think of, again, a broad definition of skin disorder, but I'm not familiar enough with all the different forms of lymphangiogenesis to specifically cite one.

Claims 10 through 12 and 17 and 18 are -- I'm sorry, not 17/18. 10 through 12 and 18 and 19 are also method claims, but they are much more specific method-of-treatment claims than the ones we have been discussing until now.

These talk about methods for treatment of symptoms associated with elevated basic fibroblast growth factor in disorders selected from -- they give a list of different disorders, and we specifically explain that you have to administer to the individual in need thereof an effective amount of pharmaceutical composition that has a curcuminoid which specifically lists a compound, in combination with a pharmaceutically acceptable carrier to inhibit angiogenesis.

And the carrier is either an ointment for topical administration containing between one-half percent and five percent of the curcuminoid or a polymer formulation for implantation.

So we have gotten really specific with these claims. Now, in many ways, these claims actually parallel the claims that were granted in the parent application. The parent application issued as a patent while this

application was being prosecuted. It's US patent number 6673843, and it has claims drawn to compositions.

The main distinction between these method-of-treatment claims and the ones that issued is that the curcuminoids in the granted claims are specified as being unsaturated curcuminoids. I think that's the main difference between the two, but they have got the same character and same polymer for implantation.

And actually, way, ages ago, during prosecution of the application, the examiner had indicated that these claims were allowable. I think they were even broader at that point. But then pulled that and lots of things have happened since then so that brings us to today.

JUDGE LINCK: We have a reference that teaches that curcuminoids are useful in inhibiting angiogenesis.

MS. MONHEIT: Right.

JUDGE LINCK: So with respect to what in your view makes the claim patentable is the amounts?

MS. MONHEIT: The amounts, yes, and also it's -- again, we are looking at treating symptoms associated with elevated bFGF levels.

And what you will see in some of the prior references is again they were really -- there's a lot of research going on about how this mechanism of action occurs, how angiogenesis occurs and there's a lot of discussion about that it inhibits one growth factor or one enzyme and just really not getting to the bFGF.

So it was something that the inventor discovered and realized also that we could use this topical carrier or this polymer for implantation,

these specific formulations can be used for treatment of these diseases and disorders and really getting at the symptoms associated with the elevated bFGF levels.

JUDGE GRIMES: What are the symptoms associated with elevated bFGF?

MS. MONHEIT: I know that -- I mean, that's one of the factors that leads to angiogenesis but it's not the only one.

JUDGE GRIMES: Okay. So angiogenesis would be a symptom associated with that. So in effect the preamble just says a method of inhibiting angiogenesis.

MS. MONHEIT: I don't think that's completely accurate because again, other factors are used in angiogenesis. So that's one of the things that it involves, but it's not the only -- there are other factors.

JUDGE GRIMES: But that is one of them.

MS. MONHEIT: If we said angiogenesis, it would be broader, is I guess where we are going.

JUDGE GRIMES: Okay.

MS. MONHEIT: I think it would be broader if you use the term -- if you substituted the term "angiogenesis" for bFGF, I think you would have a broader claim.

JUDGE GRIMES: You said that your inventor discovered that this curcuminoid acts by inhibiting bFGF action.

MS. MONHEIT: Right.

JUDGE GRIMES: If it's been used previously for inhibiting angiogenesis, doesn't the inventor's discovery just amount to figuring out how the prior process worked?

MS. MONHEIT: I don't believe so. I think that we look at -- again, they have different amounts that they are using and they are administering it in different manners, so I think when you get to a method-of-use claim and one that's this specific, you don't have the same disclosure.

JUDGE GRIMES: But if they are using amounts that encompass your amounts.

MS. MONHEIT: Let's see -- let's talk about the Aggarwal reference. I think -- is that the one you are going at? Instead of speaking in generalizations.

So Aggarwal is a nice, broad reference, and it talks about administering curcumin or an analog thereof or a flavonoid to treat pathological cell proliferative diseases. It lists a few of the different carcinomas, squamous cell carcinoma, basal cell carcinoma, and it gives you a very broad range, page 6, lines 10 to 11. The doses from one microgram to 100 milligrams.

JUDGE LINCK: They have working examples that are more specific. I think figure 6A, if my calculation is correct, they use .2 percent and they said they got 40 percent inhibition. Wouldn't it be...

MS. MONHEIT: Do you know which example that corresponds with offhand?

JUDGE LINCK: I don't know.

JUDGE GRIMES: The X axis of the graph has the curcumin concentration, micrograms per thousand.

MS. MONHEIT: Right. I was saying which example they are referring to.

JUDGE LINCK: I don't have the complete set. Do you?

MS. MONHEIT: I'm flipping. One second. I actually, have to see what they are administering. I'm sorry. I'm not finding it at this moment. If anyone else sees it, I'd appreciate your help in pointing it out to me.

I think -- it looks like this corresponds with example 1.

JUDGE LINCK: It is curcumin.

MS. MONHEIT: I'm sorry?

JUDGE LINCK: It is curcumin.

MS. MONHEIT: Yes. I'm looking at how they are administering it. Unfortunately, I don't see how they administered it. I don't see how they administer it.

This is a test. It looks like it's a test for using a different -- a cell line and treating breast tumor cells or which one is this one, HUVEC.

JUDGE LINCK: I was just responding to your very large ranges that one skilled in the art was looking at what dosages to use, the .2 percent which gave 40 percent inhibition would, it seems to suggest to one skilled in the art to go up a little bit from the .2 percent which, at the bottom of your range I believe is .5. There's also a range given in the Thaloor.

MS. MONHEIT: I'm sorry?

JUDGE LINCK: Thaloor reference.

MS. MONHEIT: Right.

JUDGE LINCK: I don't know whether you calculated the amounts that they --

MS. MONHEIT: No. I didn't have an opportunity to do that.

JUDGE LINCK: I think that is in your range. I didn't mean to put you on the spot for something that is not in the briefs, but I was looking at the calculations.

But I guess there's an overall question that I was curious about, and that has to do with the first reference. Aggarwal says use a pharmacologically effect amount. In arguing that your claims were definite earlier, you said that one of ordinary skill in the art would know how to determine --

MS. MONHEIT: What kind of assays to administer.

JUDGE LINCK: -- determine the effective amount and I don't know why the same argument would not apply to the Aggarwal reference.

MS. MONHEIT: I mean, one could figure out what is -- Aggarwal by itself doesn't, again, has this broad range. There are certain graphs showing various data points, showing what is effective and actually at what point does it kill the cells.

They have the cells die when you get to three, so it looks like at three micrograms, all the cells were dead. Clearly, there's something different about this if they are killing their cells at that point.

But the specific disclosure of the specific formulation being administered and the specific amount and specific manner that's being claimed, I mean, it's -- view claim 10 as a much more narrow claim than the

ones we were talking about before because it is so specific in the type of formulation that is being used to treat these different diseases and disorders and the amount that is being administered.

JUDGE LINCK: But that formulation was known in the art. The curcumin was known.

MS. MONHEIT: Curcumin itself was known to be -- to have anti-angiogenic properties.

JUDGE LINCK: And I think there is also teaching to use an ointment. So what is new about the formulation?

MS. MONHEIT: Again, that we are treating the symptoms associated with the elevated basic fibroblast growth factor levels.

There's a discussion about that in the Aggarwal reference and to use the specific amount of .5 percent to 5 percent in ointment or a polymer formulation for implantation is not disclosed in the Aggarwal reference. There's no discussion about fibroblast levels.

In fact, I think Aggarwal was looking at inhibiting the tyrosine kinase and phospholase kinase so they are using a different measurement and a different determination for what's effective.

With respect to the last set of -- last set of references that the examiner addressed, I have been a little bit confused. There's an Arbiser 1999 reference that was cited against us, but when we looked at the examiner's comments, they didn't seem to have anything to do with the Arbiser 1999 reference.

It wasn't clear to me upon review if he was citing just the abstract or the complete article so I looked at both because I wasn't sure which one he was getting at.

But either way, neither of these -- the Arbiser reference from 1999 doesn't talk about -- it talks about treating angiosarcoma and haemangio-endothelioma but it's using different drugs. It's using angiogenesis inhibitors of 2 methoxyestrogyl and TMP 470 and it's treating them in mice. It didn't make sense to me and --

JUDGE GRIMES: Well, I think you were right that he was actually referring to that 1998 reference that you cited in your reply brief.

MS. MONHEIT: Which one is that?

JUDGE GRIMES: It's Molecular Medicine, 1998, volume 4, pages 191 to 195.

MS. MONHEIT: Yeah. Right. This reference is -- this is the Molecular Medicine 1998 Arbiser article. This one actually does address curcumin as an anti vivo inhibitor angiogenesis. This focuses on --

JUDGE GRIMES: I'm sorry. The one I'm looking at talks about recessive dystrophic epidermolysis bullosa.

MS. MONHEIT: I don't --

JUDGE GRIMES: I'm sure this is the one you cited in the reply brief.

MS. MONHEIT: Let me see if I have it in another file. This is why I bring all the files with me.

JUDGE GRIMES: It's cited on page 10 of the reply brief.

MS. MONHEIT: No. I pulled a different one from 1998 so it's not something that I have before me.

JUDGE GRIMES: Let me characterize it.

MS. MONHEIT: I think there are a few sentences in here, but -

JUDGE GRIMES: I can give you the quotes that I highlighted. Patients with recessive dystrophic epidermolysis bullosa have deficiencies of collagen type 7 and have elevated levels of fibroblast collagenase.

And then in their conclusions they say we have found that patients with RDEB, have elevated levels of bFGF, which may contribute to increased fibroblast collagenase and the development of squamous cell carcinoma. These results suggest a novel treatment for RDEB, namely, angiogenesis inhibitors which may antagonize the effects of bFGF in this disorder.

I think that's what the examiner was relying on in trying to get to claim 18. That's a suggestion to use an angiogenesis inhibitor to treat RDEB and then combining it with the other references which tell you that curcumin is a known angiogenesis. So if we assume that that's what the reference actually says --

MS. MONHEIT: Like a blindfold. My understanding from the limited disclosure I have in front of me is that at that point, Arbiser's reference is looking at different possible rationales for what's going on.

There's discussion of some other options that may be rationales for why the agent is effective as an angiogenesis inhibitor and is not solely directed to the bFGF inhibition of the bGBF levels. Do you have the reference in front of you?

They also talked about that there is a lack of clarity about what's going on there.

Also, I can't tell from the reference I don't have before me but whether or not they are actually discussing the administration of the specific formulations that we are talking about, the ointment, namely, the ointment and the polymeric implant that contains curcumin for the treatment of these specific disorders. So thank you for reading something to me.

The last reference that is cited against us is the Thaloor which Judge Linck was beginning to discuss. Again, just to link back to our previous discussion about lymphangiogenesis and angiogenesis, a number of these references have been disclosing definitions for angiogenesis and the ones that I kept seeing were processes of generating new blood vessels over and over again.

This would be another one on page 305. They define it as a process of generating new blood vessels.

The Thaloor reference describes administering a new class of drugs, and it talks about administering these angiogenesis inhibitors to treat uncontrolled angiogenesis, and it doesn't treat the specific formulations that we have been talking about nor disclose the inhibition of beta FGF levels, and it really doesn't add anything to the disclosures of Aggarwal or Arbiser from '98 or '99.

It states that mechanism of action in curcumin with regard to how it binds the cell induces its effect is not known. This is on page 309. It's speculating about how it behaves and it's just not clear.

It suggests further study of curcumin as an anti-cancer agent. So it's not clear about what the effective amounts would be, not clear about treatment of beta FGF levels or what amounts would be appropriate for that, let alone the administration of specific formulations for treatment of specific disease and disorders listed in claims 10 and its dependent claims.

That's all I have. Thank you so much.

JUDGE SCHEINER: Does anyone have questions?

JUDGE LINCK: I don't.

JUDGE SCHEINER: Is that everything.

MS. MONHEIT: That's all I have. Thank you so much.

MS. SCHEINER: Thank you for coming in.

MS. MONHEIT: I want to mention that Patria Pabst would have liked to have been here presenting this but she is off in Munich for another hearing.

(Whereupon, the proceedings at 10:05 a.m. were concluded.)